

**Notice of Allowability**

Application No.

10/031,005

Examiner

Holly Schnizer

Applicant(s)

NELSESTUEN, GARY L.

Art Unit

1656

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 7/27/06 & 8/31/06.
2. ☒ The allowed claim(s) is/are 76,80,81,85-102 and 117-151.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 7/27/06 & 8/18/06
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 7/27/06 has been entered.

***Status of the Claims***

The amendment filed 8/31/06 has been entered and considered. Claims 117-151 have been added. Claims 76, 80, 81, 85-102, and 117-151 are pending. It is noted that Claims 76, 96, 98, 99, and 102 were indicated as being "previously presented" but were actually amended to correct grammatical errors. The claims have been considered in their entirety and do not contain new matter.

***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance:

The Amendment and IDS filed 7/27/06 have been entered and considered. The amendment to the Specification changing the Priority has been considered and the art of record has been reevaluated in light of this change. Reference AA (US Patent No. 6,806,063) of the IDS filed 7/27/06 teaches a factor VII polypeptide with a modified GLA

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domain comprising an amino acid substitution that is a glutamic acid residue at position 34 (A34E, see Col. 19, lines 24-27). The '063 patent claims priority to a provisional application (60/184,036) filed February 22, 2000, which is before the filing date of the present invention. However, the provisional application does not appear to teach or suggest the factor VII with the A34E substitution. Thus, the '063 patent is not considered to be prior art over the present claims. In addition, reference AS (US 2003/0100506) of the IDS filed 8/18/06 teaches a factor VII polypeptide with a substitution at position 35 to glutamate (E35, see p. 22 Table 8, last mutant in the Table). It is noted that the '591 application uses the numbering according to Factor IX. Factor IX has an extra amino acid at position 4 that is not present in factor VII (see alignment in McDonald et al. (Biochemistry (1997) 36: 5120-5127 at p. 5125; cited in IDS) for example). Therefore, position 35 in the '506 publication, is the same as position 34 of SEQ ID NO:3 (factor VII) disclosed in the present application. The '506 publication is a continuation-in-part of US application 09/497,591 (now US Patent No. 6,747,003) filed 2/3/2000 which is before the filing date of the present invention. However, the '591 application does not disclose or suggest the factor VII with the substitution of glutamate at position 34 (position 35 according to the numbering of the '591 application. Therefore, the '591 application is not considered to be prior art over the present claims.

Therefore, Claims 76, 80-81, 85-102, and 117-151 are allowable for reasons of record.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-0958. The examiner can normally be reached on Tuesday-Thursday from 10 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Holly Schnizer  
August 17, 2006



KATHLEEN M. KERR, PH.D.  
SUPERVISORY PATENT EXAMINER